IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA *ex rel.* [ANONYMOUS],	)	
	)	Civil Action No.:
Plaintiffs,	)	**FILED IN CAMERA AND UNDER SEAL IN ACCORDANCE WITH THE FALSE CLAIMS ACT 31 U.S.C. § 3730(b)(2)**
v.	)	
[ANONYMOUS],	)	**DO NOT PLACE IN PRESS BOX**
Defendant.	)	**DO NOT ENTER ON PACER**
	)	**JURY TRIAL DEMANDED**

COMPLAINT

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA *ex rel.* JAMES THOMPSON, Plaintiffs, v. McKESSON CORPORATION, Defendant.	)	Civil Action No.: **FILED IN CAMERA AND UNDER SEAL IN ACCORDANCE WITH THE FALSE CLAIMS ACT 31 U.S.C. § 3730(b)(2)** **DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER** **JURY TRIAL DEMANDED**

COMPLAINT

I. NATURE OF THE ACTION

1. Plaintiff-Relator James Thompson brings this False Claims Act ("FCA") action on behalf of the United States of America against McKesson Corporation ("McKesson" or "Defendant") to recover hundreds of millions of dollars that McKesson fraudulently caused Medicare and Medicaid to pay in the form of Electronic Health Record incentive payments ("Incentive Payments") and false claims for healthcare services from 2011 through at least 2015.

2. From 2010 through at least 2012, McKesson fraudulently represented and marketed its Electronic Health Record ("EHR") product "Horizon Clinicals" as part of a scheme to increase its profits by inducing hospitals to purchase this fundamentally flawed software and use it to obtain Medicare and Medicaid payments to which they were not legally entitled. McKesson also engaged in fraud to obtain government certification for Horizon Clinicals, a mandatory predicate to maintaining a market for its product. These interrelated and unlawful acts combined to defraud the government on a massive scale.

3. Electronic Health Record systems enable hospitals and other healthcare providers to coordinate patient care across various delivery settings, ensuring that each provider has access to the information necessary to properly, efficiently, and safely treat patients.

4. The federal government recognized that Electronic Health Records had great potential to improve healthcare, but could also cause great harm to the provision of safe and effective healthcare if they did not function properly. To encourage hospitals to invest the millions of dollars needed to purchase and use a foundationally sound EHR system, the government established programs under Medicare and Medicaid to pay Incentive Payments for owning and using EHRs certified against a federal standard. These programs have been allocated billions of

dollars of public funds, much of which has already been paid out to hospitals pursuant to federal laws and regulations.

5. In order to become eligible to receive Medicare and Medicaid Incentive Payments, a hospital must purchase an EHR product that has been "certified" by an accredited certification body using standards set by federal law, and must be able to use that certified EHR in accordance with the federal standard for "meaningful use." The main purpose of this certification is to ensure the EHR is sufficiently functional for safe and effective clinical care.

6. McKesson is a Fortune 15 company and the manufacturer and seller of Horizon Clinicals and other EHR products. Knowing that under federal law only a certified EHR system would allow hospitals to obtain Medicare and Medicaid Incentive Payments, and seeking to quickly capture market share for Horizon Clinicals, McKesson set out to obtain certification for it quickly and by any means necessary.

7. Horizon Clinicals was at all relevant times an unworkable conglomerate of separately-developed or -purchased programs, and as such did not provide the real-life functionality legally mandated by the federal certification process and "meaningful use" standards. Rather than devote the time and resources needed to improve its product to satisfy the minimum standards required by law, McKesson decided to take a shortcut and "game" the certification process. To do so, McKesson modified Horizon Clinicals' software code to artificially mimic the required functionality being tested during the certification process, while knowing full well that the system would not provide that functionality to its real-world users when the treatment and lives of patients depended on it.

8. For example, a hospital using Horizon Clinicals would not be able to track a single patient's electronic health record from their initial visit to its Emergency Department, through

their admission to the hospital as an inpatient, and ultimately to an appropriate discharge. Information entered through one "workflow" within Horizon Clinicals – such as the Emergency Department interface – would not accurately be recalled by another workflow such as that used by a hospital physician for inpatient treatment. That physician would not reliably be shown vital information about the patient, including their allergies, what medications they are taking, or even what problems brought them to the Emergency Department in the first place. This is because Horizon Clinicals was not the integrated, unified system that McKesson marketed, but instead was an ineffective and dangerous hodgepodge of separately-developed systems, each of which had multiple competing mechanisms by which to enable a given function that should have been contained within a single, coherent workflow.

9. McKesson's fraudulent scheme was multifaceted. The first step was to fraudulently obtain certification for Horizon Clinicals; the second step was to rely upon deceitful sales promotions (which, among other tactics, showcased the fraudulently obtained certification) to convince hospitals to choose Horizon Clinicals over the legitimately certified EHR systems offered by its competitors. The final step necessarily followed from the first two: to cause those hospitals who purchased Horizon Clinicals to submit false claims to Medicare and Medicaid for Incentive Payments.

10. This scheme was financially successful by any measure. After having Horizon Clinicals certified, McKesson sold or continued to implement Horizon Clinicals systems to roughly 600 hospitals or hospital systems, nationwide. These hospitals received close to $1 billion in Medicare and Medicaid EHR Incentive Payments during the years 2011-2014 alone, and perhaps more. McKesson directly benefited from these Incentive Payments that were intended to subsidize the cost of acquiring EHR systems, achieving hundreds of millions of dollars from

direct Horizon Clinicals sales or ancillary products whose sales were fundamentally connected to Horizon Clinicals.

11. Notably, the fundamental flaws of Horizon Clinicals impaired the ability of hospitals using that software to generate and submit accurate Medicare and Medicaid claims for reimbursement for healthcare services performed at their facilities. When an EHR is dysfunctional, services billed do not meet basic accuracy standards required by third party payers such as CMS. A dysfunctional EHR will mis-code diagnoses and procedures not only for treatment but also billing purposes. McKesson's fraudulent marketing and sale of Horizon Clinicals thereby caused hundreds of hospitals to submit false claims to Medicare and Medicaid for payment.

12. Unfortunately, the impact of McKesson's fraud was not limited even to these entities, but negatively affected the safety and quality of healthcare received by the thousands upon thousands of patients whose providers did not have access to the level of EHR functionality they believed they had purchased from McKesson. In the end, Medicare and Medicaid were made to pay billions of dollars in services to hospitals that never obtained the EHR functionality the government sought and required.

13. More broadly, McKesson's fraud severely impeded the government's laudable attempt to drive broader acceptance and use of EHR systems to improve clinical care. By falsely representing as "government certified" a fatally flawed and unworkable EHR, the entire multi-billion dollar EHR Incentive Program suffered serious reputational damage wherever Horizon Clinicals was installed. Users of Horizon Clinicals perceived the government's initiative as ineffective and counter-productive because the "certified" EHR with which they were presented interfered with safe and effective care rather than facilitating it.

14. In an extraordinary reflection of Horizon Clinicals' intractable problems, virtually all customers have already abandoned Horizon Clinicals and been forced to replace it with another EHR system. Those few still using the system have been told by McKesson that they must transition to another EHR, despite having been reassured during the original sales process that McKesson would devote the resources to maintain the viability of Horizon Clinicals.

15. In addition to causing the submission of false claims to Medicare and Medicaid for payment of medical services, McKesson's actions as set forth herein gave rise to multiple violations of the federal False Claims Act in at least the following respects:

a) McKesson knowingly caused hospitals to present to Medicare and Medicaid false claims for Incentive Payments under the American Recovery and Reinvestment Act (ARRA) because Horizon Clinicals obtained certification as an EHR system -- a statutorily-imposed necessary predicate to obtaining an EHR Incentive Payment -- by means of fraud;

b) McKesson knowingly made statements material to false claims, namely, that Horizon Clinicals was "certified" pursuant to ARRA, while omitting the critical fact that such certification had been obtained by means of fraud and thus rendering that statement false and misleading;

c) McKesson knowingly caused to be made false statements material to false claims because it deliberately deceived the accredited certification body into concluding that Horizon Clinicals possessed the functionality required to be "certified" as an EHR system pursuant to ARRA when it did not; and

d) McKesson knowingly presented claims for payment to its hospital customers who purchased Horizon Clinicals that were grounded in fraud because:

1) Horizon Clinicals' EHR certification was the product of fraud on McKesson's part, and

2) McKesson fraudulently misrepresented the functionality of Horizon Clinicals to its customers.

Furthermore, the hospital customers were "grantees" of the United States who were using the EHR Incentive Payments to acquire and integrate EHR functionality into the hospital and thereby advance a federal government program.

II. JURISDICTION & VENUE

16. This Court has jurisdiction under 31 U.S.C. §§ 3730 *et seq.* and 28 U.S.C. §§ 1331 and 1345. This Court may exercise personal jurisdiction over the Defendant because it resides and/or transacts business in this District or committed the proscribed acts in this District. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) in that many of the acts complained of took place in this District and/or the Defendant can be found, resides, or transacts business in this District.

III. PARTIES

17. The United States of America is the real party in interest to the claims of this action.

18. The United States brings this action on behalf of the Department of Health and Human Services and the Centers for Medicare & Medicaid Services ("CMS"), which administer the Medicare and Medicaid programs.

19. Relator James Thompson is an experienced medical doctor who presently works on the Clinical Integration Team for a medical terminology and healthcare technology company in

Illinois. Relator is Board Certified by the American Board of Internal Medicine and the American Board of Emergency Medicine. He is a licensed physician in Illinois and has worked in various roles in the healthcare field for over three decades, including as a University-based Assistant Clinical Professor of Medicine, a medical director and attending physician in emergency departments, and as the Medical Director-Informatics for Central DuPage Health hospital system in Illinois from 1997-2007.

20. Relator's combined clinical, academic, and medical informatics background has provided him with extensive knowledge regarding the functionality an EHR system should provide and, in contrast, how Horizon Clinicals actually worked in practice at the Central DuPage Health system. Relator had personal contact with dozens of major Horizon Clinicals customers during his roles at Central DuPage as well as his roles within McKesson. This contact was firsthand at user group meetings, personal and professional meetings, McKesson-assigned customer meetings and the like.

21. Relator was employed by McKesson from 2005 through May 2013, as Vice President for Medical Affairs, where he was primarily responsible for sales presentations and customer relationships, as well as (from 2011-2013) an advisory role into development strategy for Horizon Clinicals. At McKesson, Relator participated in the sales process for both individual components of and the "complete" EHR McKesson Horizon Clinical suite. Relator became a highly successful member of the sales team, achieving the award for Solutions Consultant of the Year in 2009—a record year during which his business unit achieved several hundred million dollars in total sales, much of it related directly or indirectly to Horizon Clinicals.

22. Relator was the McKesson physician who presented Horizon Clinicals to the Drummond Group, the accredited certification body that administered the Meaningful Use ("MU") Stage 1

Certification examination in 2010, which resulted in MU certification for Horizon Clinicals. In 2011, Relator was transferred from a sales-oriented role to a role with the Horizon Clinicals development group.

23. Defendant McKesson is a Delaware corporation, whose stock trades on the New York Stock Exchange (ticker: MCK) and whose principal executive offices are located at One Post Street, San Francisco, California 94104. McKesson had total revenue of over $179 billion in its fiscal year 2015, and states that more than half of U.S. hospitals use its technology and services.[1]

IV. THE FALSE CLAIMS ACT

24. The False Claims Act ("FCA") provides in pertinent part that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim

is liable to the United States Government [for treble damages and such penalties as are allowed by law].

31 U.S.C. § 3729(a)(1)(A) and (B).

25. The FCA further provides that "knowing" and "knowingly"

> (A) mean that a person, with respect to information-
>
> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud[.]

[1] "Key Facts," McKesson Website, available at http://www.mckesson.com/about-mckesson/key-facts/.

31 U.S.C. § 3729(b)(1).

26. A "claim," as that term is used in the False Claims Act, means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that – (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government – (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded …." 31 U.S.C. § 3729(b)(2).

27. Section 3729(a)(1) of the FCA provides that a person is liable to the United States for three times the amount of damages which the Government sustains because of the act of that person, plus, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note, a civil penalty of $5,500 to $11,000 per violation.

V. MEDICARE AND MEDICAID

28. Congress established the Medicare Program in 1965 to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. See 42 U.S.C. §§ 426 & 426a.

29. Medicare will only cover those services or goods that are reasonable and necessary and that meet professionally recognized standards of health care. 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1320c-5(a)(2).

30. In order to assess the reasonableness and necessity of those services and whether payment is appropriate, Medicare requires proper and complete documentation of the services rendered to beneficiaries. In particular, the Medicare statute provides that:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e).

31. Medicaid is a joint state-federal health benefit program for the poor.

32. To be covered by Medicare or Medicaid, services must not only be medically necessary, they must also be provided in the most economical manner. This economical manner requirement is set forth in multiple federal statutes and CMS regulations prescribing the responsibilities and obligations of health care practitioners, providers of health care services, and contractors who review claims for payment.

A. Electronic Health Records And The Medicare And Medicaid Electronic Health Record Incentive Programs

1. Background on EHR Technology, Functionality, and Evolution

33. Electronic Health Records are "the portions of a patient's medical records that are stored in a computer system as well as the functional benefits derived from having an electronic health record."[2]

34. Beginning in the late 1990s, healthcare providers rapidly accelerated their transition from paper to electronic health records, creating a large and expanding marketplace for EHR software vendors.

35. By 2005 and increasingly since then, marketplace sentiment shifted heavily toward single-vendor EHR suites for the vast majority of patient care within a given healthcare enterprise, because of the unworkable nature of creating an integrated suite from multiple vendors who developed the EHR components independently.

[2] Richard Gartee, Electronic Health Records: Understanding and Using Computerized Medical Records, 4-5 (2nd ed., Pearson Education, Inc. 2011).

36. A primary benefit of EHR systems is their promotion of safe and effective healthcare. Safe healthcare is improved when critical clinical data moves throughout the continuum of care without loss of integrity, and can be acted upon with confidence by the clinician using and relying on that data to make decisions on patient care.

37. Healthcare enterprises are responsible for taking care of patients across a wide variety of clinical situations such as an office visit, Emergency Department visit, or inpatient care. Taking care of a given patient safely and effectively means that information must be able to flow across all of those settings of care, and among all of the clinicians involved with the care of any given patient. A properly-designed electronic health record can more efficiently (than on paper) distribute information, and make it easier to maintain data integrity for elements that need to be shared across settings of care through the use of centrally-accessed files and uniform data standards.

38. As explained by the Congressional Budget Office, when used effectively EHRs can prompt providers to prescribe cost-effective generic medications, remind physicians about preventive care options, and reduce unnecessary or duplicative diagnostic tests.[3]

39. A functional EHR will also prevent medical errors, improving patient safety and reducing waste in healthcare delivery. Preventable medical errors were estimated to result in costs of over

[3] Congressional Budget Office, "Evidence on the Costs and Benefits of Health Information Technology," at 1 (May 2008), available at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/05-20-healthit.pdf.

$19 billion in 2008 alone.[4] In addition, medical errors have recently been ranked as the third largest cause of death in the United States.[5]

40. The functions provided by an effective EHR are particularly important in the hospital setting:

> Data are gathered more frequently during the inpatient's stay, resulting in a substantially large amount of information gathered during a short period of time. In most hospitals, a new chart or medical record is started for each hospital stay …. Because a large number of caregivers are involved with the patient's stay in an acute care facility, there are a larger number of individuals with a legitimate need to access a patient's record than in an ambulatory care setting. These caregivers include not only nurses and physicians, but other specialists that may consult on the case; radiologists, respiratory therapists, dieticians, and in many hospitals, even the hospital pharmacists have access to the records when consulting with the ordering physicians about the medications being prescribed.[6]

41. EHR systems operate not only to allow providers access to critical and accurate patient information at the point of care, but also incorporate that information into a provider's billing system. EHR programs will typically use diagnosis and procedure data to generate claims for payment to be submitted to Medicare, Medicaid, and other insurers. A fundamentally flawed EHR will not provide accurate patient information at the point of care, and will therefore result in the provision of services that are not reasonable and necessary and therefore not covered by Medicare and Medicaid.

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[4] Charles Andel, et al., "The Economics of Health Care Quality and Medical Errors," Wolters Kluwer Journal of Health Care Finance, Vol. 39, No. 1 (Fall 2012), available at http://www.wolterskluwerlb.com/health/resource-center/articles/2012/10/economics-health-care-quality-and-medical-errors.

[5] "Researchers: Medical errors now third leading cause of death in United States," THE WASHINGTON POST (May 3, 2016), available at https://www.washingtonpost.com/news/to-your-health/wp/2016/05/03/researchers-medical-errors-now-third-leading-cause-of-death-in-united-states/ (last visited May 5, 2016).

[6] Richard Gartee, Electronic Health Records: Understanding and Using Computerized Medical Records, 24 (2nd ed., Pearson Education, Inc. 2011).

42. Hospitals will typically use information from EHR systems to support the billing codes they use in healthcare claims to Medicare and Medicaid.

43. Some EHR systems have the capability to directly create healthcare billing claims, often as an add-on service.

44. In fact, Horizon Emergency Care (HEC) was software originally developed primarily to enable Emergency Departments to increase their billing revenues. McKesson purchased the HEC software module but was ultimately unable to properly integrate it into the Horizon Clinicals suite.

2. The Medicare EHR Incentive Program

45. The Health Information Technology for Economic and Clinical Health Act (HITECH), enacted in 2009 as part of the American Recovery and Reinvestment Act (ARRA), established a variety of programs as part of a national initiative to improve American healthcare delivery and patient care through an unprecedented investment in health information technology.

46. A cornerstone of this initiative is the ONC (Office of the National Coordinator) Health IT Certification Program (IT Certification Program). Using an initial allocation of $19 billion dollars, the IT Certification Program provides for Medicare and Medicaid to award generous financial incentives ("Incentive Payments") to healthcare providers who promptly acquire and put to "meaningful use" a sufficiently capable EHR system while penalizing those who do not.

47. The certification process is the backbone of the IT Certification Program because before any healthcare provider can receive any financial incentives, the EHR it utilizes must contain a minimum level of very specifically-defined foundational functionality critical for safe patient care as demonstrated by being officially "certified" by a government-designated review body. Responsibility for obtaining this certification was assumed by EHR providers, such as McKesson.

48. CMS issued a final rule governing the IT Certification Program on July 28, 2010 that "implement[ed] the provisions of ARRA (Pub. L. 111–5) that provide incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs) participating in Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology." 75 Fed. Reg. 44313 (July 28, 2010) (the "Final Rule").

49. The incentive payment structure implemented by the Final Rule is "part of a broader effort under the HITECH Act to accelerate the adoption of [health information technology] HIT and utilization of qualified EHRs." Final Rule at 44316.

50. The Final Rule sets forth the eligibility requirements for incentive payments beginning in FY2011 and the negative adjustments to reimbursement rates beginning in FY2015 for non-adopting hospitals. Final Rule at 44316.

51. Medicare Incentive Payments are available to qualifying eligible professionals, hospitals, and Critical Access Hospitals.

52. The first requirement for a hospital to receive a Medicare Incentive Payment is to obtain a "certified" EHR. The HITECH Act defines "certified EHR technology" as:

> "*(1) CERTIFIED EHR TECHNOLOGY.-The term 'certified EHR technology' means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals.*" (HITECH Act § 3000(1)).

And it defines "qualified electronic health record" as:

> *''(13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term 'qualified electronic health record' means an electronic record of health-related information on an individual that— ''(A) includes patient demographic and clinical health information, such as medical history and problem lists; and ''(B) has the capacity— ''(i) to provide clinical decision support; ''(ii) to support physician order entry; ''(iii) to capture and query information relevant to health*

> *care quality; and ''(iv) to exchange electronic health information with, and integrate such information from other sources.*" (HITECH § 3000(13)).

53. The Final Rule describes certified EHR technology as "a critical component" of the EHR Incentive Programs. Final Rule at 44317.

54. "Certified EHR technology used in a meaningful way is one piece of a broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. HHS believes this ultimate vision of reforming the health care system and improving health care quality, efficiency and patient safety should drive the definition of meaningful use consistent with the applicable provisions of Medicare and Medicaid law." Final Rule at 44321.

55. "Ultimately, consistent with other provisions of law, meaningful use of certified EHR technology should result in health care that is patient centered, evidence-based, prevention-oriented, efficient, and equitable." Final Rule at 44321.

56. A hospital seeking Medicare Incentive Payments must not only obtain a certified EHR but must also demonstrate "Meaningful Use" of that technology. The Final Rule defines "meaningful use" as: use of (a) certified EHR in (b) meaningful way, and (c) submission of clinical quality measures (CQM) data to CMS. See Final Rule at 44324.

57. As explained in the Final Rule:

> "*[A]n [eligible provider] and an eligible hospital shall be considered a meaningful EHR user for the relevant EHR reporting period for a payment year if they meet the following three requirements (1) Demonstrates use of certified EHR technology in a meaningful manner; (2) demonstrates to the satisfaction of the Secretary that certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care such as promoting care coordination, in accordance with all laws and standards applicable to the exchange of information; and (3) using its certified EHR technology, submits to the Secretary, in a form and manner specified by the*

Secretary, information on clinical quality measures and other measures specified by the Secretary." Final Rule at 44324.[7]

58. For hospitals, the Final Rule requires demonstration of a "core set" of 14 "meaningful use objectives":

—Use CPOE [Computerized Physician Order Entry]
—Implement drug to drug and drug allergy interaction checks
—Record demographics
—Maintain an up-to-date problem list
—Maintain active medication list
—Maintain active medication allergy list
—Record and chart changes in vital signs
—Record smoking status
—Implement one clinical decision support rule
—Report CQM [Clinical Quality Measures] as specified by the Secretary
—Electronically exchange key clinical information
—Provide patients with an electronic copy of their health information
—Provide patients with an electronic copy of their discharge instructions
—Protect electronic health information created or maintained by certified EHR

Final Rule at 44328; 42 C.F.R. § 495.6(f).

59. Hospitals must also complete 5 objectives out of 10 from a menu set, and report to CMS on 15 clinical quality measures. 42 C.F.R. § 495.6(g).

60. The Medicare Incentive Program provides for three Stages of Meaningful Use. Stage 1 ("MU1") is the foundational framework for the later expansion of providers' EHR adoption and use.

61. "*Stage 1*: The Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focuses on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support

[7] See also 42 U.S.C. § 1395ww(n) (definition of "Meaningful EHR User").

tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information. Stage 1 focuses heavily on establishing the functionalities in certified EHR technology that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in certified EHR technology at the outset of the program and requiring that the EP, eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we will create a strong foundation to build on in later years." Final Rule at 44321 (emphasis added).

62. For MU1, the Final Rule includes "Measures" that hospitals must meet to qualify for Meaningful Use. For example, "more than 30% of unique patients with at least one medication in their medication list … admitted to the eligible hospital's … inpatient or emergency department [] have at least one medication order entered using CPOE." Final Rule at 44377.

63. Hospitals who achieve MU1 have a period of time, generally two to three years, to reach Meaningful Use Stage 2 ("MU2"). MU2 builds upon the foundation of MU1 and adds new core and menu objectives, and higher levels of required functionality.[8]

64. The EHR Incentive Programs currently provide for Meaningful Use Stage 3 ("MU3") to begin in 2018.[9]

[8] See generally "Stage 2 Overview Tip Sheet," Centers for Medicare & Medicaid Services (August 2012), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2Overview_Tipsheet.pdf

[9] See generally CMS Website at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2015ProgramRequirements.html

3. The Amount and Calculation of Medicare Incentive Payments and Penalties

65. Hospitals that become eligible for Medicare Incentive Payments will receive an annual payment equal to the product of an "Initial Amount," the "Medicare Share," and a "Transition Factor." 42 U.S.C. § 1395ww(n); 42 CFR § 495.104.

66. The Initial Amount for eligible hospitals is measured in the millions of dollars: a $2 million base amount plus an additional amount of up to $4,370,400 based on a given hospital's number of acute care discharges for that year, for a total potential payment of $6,370,400.[10]

67. The Medicare Share is generally the percentage of a hospital's bed-days that are paid for by Medicare.[11]

68. The Transition Factor is a number from 1 to 0.25 that reflects how quickly a hospital attained eligibility and for how many years it has received incentive payments. For example, a hospital will have a 1.00 Transition Factor in its first year of eligibility if that year is 2011-2013, and will have a smaller Transition Factor in subsequent years of eligibility.[12] The Transition Factor provides an incentive for hospitals to quickly integrate EHR systems.

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[10] Eligible hospitals will receive a discharge-related amount equal to $200 for each acute care discharge after a hospital's 1,149th discharge and up to its 23,000th discharge, for a maximum total of $4,370,400. See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MLN_TipSheet_MedicareHospitals.pdf

[11] Technically, it is calculated by dividing the estimated number of inpatient-bed-days attributable to patients covered by Medicare Part A or by a Medicare Advantage organization under Part C, by the estimated total number of inpatient-bed-days during the prior year plus certain additional charges. See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MLN_TipSheet_MedicareHospitals.pdf

[12] See "EHR Incentive Program for Medicare Hospitals: Calculating Payments," CMS Website at 3 (May 2013), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MLN_TipSheet_MedicareHospitals.pdf

69. Hospitals that become eligible for Incentive Payments beginning in years 2011-2013 are eligible for up to four years of Incentive Payments, while hospitals that first become eligible in 2014 and 2015 are eligible for up to three and two years of Incentive Payments, respectively.[13]

70. The HITECH Act also established a penalty system for hospitals that did not achieve Meaningful Use by 2015. These hospitals will receive a reduced update to their inpatient prospective payment system (IPPS) amount for FY2015 and each subsequent year of non-compliance.

71. The penalty provision "establishes a continuing incentive for hospitals to become meaningful EHR users, because a hospital that does become a meaningful user in any year after the effective date of the update reduction will receive the same, fully updated standardized amount for that year, and subsequent years, as those hospitals that were already meaningful EHR users at the time when the update reduction went into effect[]." Final Rule at 44460.

72. The financial incentives contained in the HITECH Act have been immensely successful. As of December 2015, nearly 5,000 hospitals – approximately 90% of all hospitals in the country – registered for Medicare Incentive Payments, with the vast majority dually-registered for Medicaid Incentive Payments as well.

73. As of 2015, these hospitals have applied for and CMS has paid a total of over $11.6 billion in Incentive Payments for Stage 1 MU.[14]

[13] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MLN_TipSheet_MedicareHospitals.pdf.

[14] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/December2015_SummaryReport.pdf.

4. The Medicaid EHR Incentive Program

74. Acute care hospitals[15] and children's hospitals[16] are eligible to receive incentive payments under Medicaid as well as Medicare. 42 C.F.R. § 495.302.[17]

75. Medicaid Incentive Payments were first awarded beginning in 2011. Medicaid payments are disbursed to eligible hospitals over a 3-6 year period, and the last year that a hospital may begin receiving Medicaid Incentive Payments is FY2016. Final Rule at 44499.

76. "The HITECH Act allows Medicaid EPs and eligible hospitals to receive an incentive for the adoption, implementation, or upgrade of certified EHR technology in their first participation year . In subsequent years, these EPs and eligible hospitals must demonstrate that they are meaningful users." Final Rule at 44319; 42 C.F.R. § 495.314(a), (b). Thus, in the first year, otherwise eligible hospitals need not fulfill MU requirements to receive Medicaid Incentive Payments.

77. "Adoption, implementation, or upgrade" is defined as:

> *(1) Acquire, purchase, or secure access to certified EHR technology; (2) Install or commence utilization of certified EHR technology capable of meeting meaningful use requirements; or (3) Expand the available functionality of certified EHR technology capable of meeting meaningful use requirements at the practice site, including staffing, maintenance, and training, or upgrade from existing EHR technology to certified EHR technology per the ONC EHR certification criteria.*

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[15] Those with average lengths of stay (ALOS) equal to or less than 25 days and a CMS Certification Number (CCN) between 0001-0879 or 1300-1399. Acute care hospitals must have at least 10% of their patients ("patient encounters") covered by Medicaid. 42 C.F.R. § 495.304(e).

[16] Hospitals that have CCNs between 3300-3399.

[17] Final Rule at 44317 ("Eligible hospitals and CAHs may participate in both the Medicare program and the Medicaid program, assuming they meet each program's eligibility requirements, which vary across the two programs"); Final Rule at 44482 ("Under the HITECH Act, State Medicaid programs, at their option, may receive Federal financial participation (FFP) for expenditures for incentive payments to certain Medicaid providers to adopt, implement, upgrade, and meaningfully use certified EHR technology.")

42 C.F.R. § 495.302.

78. The federal financial participation (FFP) for Medicaid Incentive Payments is 100% and is 90% for costs of administering the program. 42 C.F.R. §§ 495.320 and 322.

79. Accordingly, each State's Medicaid Program is a "grantee" of federal funds pursuant to 31 U.S.C. § 3729(b)(2), and false claims submitted to Medicaid Programs are violations of the federal False Claims Act.

80. The amount of a given eligible hospital's annual Medicaid Incentive Payment is calculated similarly to that under Medicare: a base amount of $2 million plus $200 per discharge within certain thresholds, multiplied by a transition factor of 1.0 to 0.25, multiplied by the Medicaid Share (the share of a hospital's inpatient non-charity care days attributable to Medicaid inpatients). Final Rule at 44498; 42 C.F.R. § 495.310.

81. The process for submitting Medicaid Incentive Payment claims varies by state but in all events includes an attestation by the hospital that it has met the legal requirements for adoption, implementation, or upgrade of a certified EHR, 42 C.F.R. § 495.314(a), or for meaningful use of a certified EHR, 42 C.F.R. § 495.8(b)(1)(i).

82. Specifically, providers must sign on "any forms on which a provider submits information necessary to the determination of eligibility to receive EHR payments," the following statement: "This is to certify that the foregoing information is true, accurate, and complete. I understand that Medicaid EHR incentive payments submitted under this provider number will be from Federal funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws." 42 C.F.R. § 495.368(b).

83. Medicaid has paid over $6.2 billion in Incentive Payments to eligible hospitals as of May 2016, approximately evenly split between payments for "adoption, implementation, or upgrade" and for Meaningful Use.[18]

B. The EHR Testing And Certification Process

84. The Medicare and Medicaid Incentive Programs require a robust testing and certification process for EHR software to become "certified" in order to ensure that only EHR capable of performing at a certain baseline level of functionality will be marketed, purchased, and ultimately result in Incentive Payments.

85. This aspect of the Medicare and Medicaid Incentive Programs was directed toward software vendors, who had the ultimate control over what products they developed, submitted for certification, and sold into the marketplace as "Certified Electronic Healthcare Technology."

86. As explained in the Final Rule, the certification requirement provided critical assurance that Meaningful Use requirements could indeed be reasonably achieved:

> *One of the main purposes of certifying EHR technology is to provide the EP, eligible hospital, or CAH with confidence that the technology will not be the limiting factor in the achievement of meaningful use .... We explicitly link each meaningful use objective to certification criteria for certified EHR technology .... This way we ensure that certified EHR technology can accomplish meaningful use and meaningful use has the intended consequences of improving the healthcare priorities that make up meaningful use."* Final Rule at 44331.

87. While the government could have tested and certified EHR technologies directly, it chose instead to oversee a structure in which private organizations administer the testing and certification processes under standards set by federal and state law.[19]

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[18] See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2016_MedicaidEHRIncentivePayments.pdf

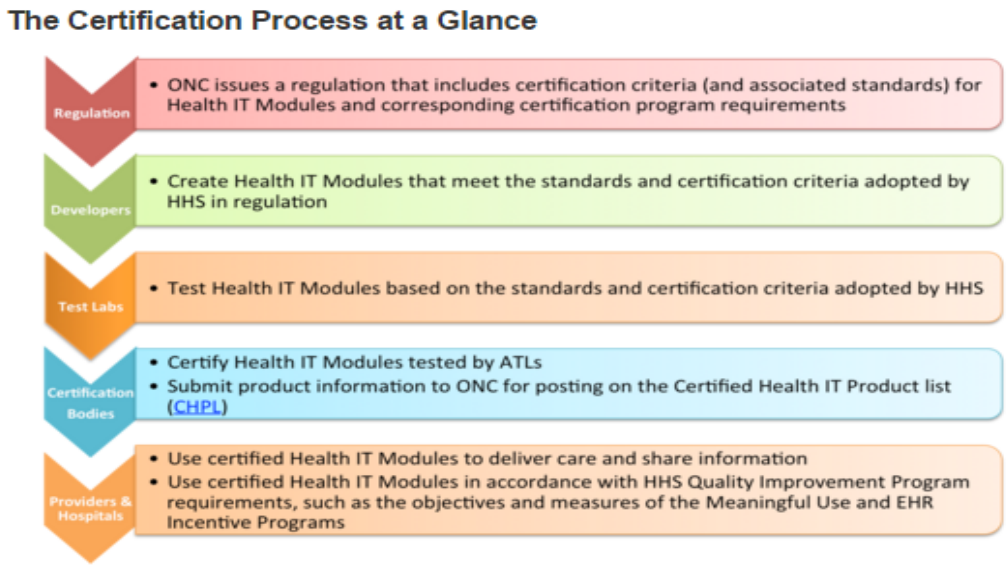
[19] The National Coordinator approves a single ONC-Approved Accreditor ("ONC-AA") at a time, which is responsible for accrediting ONC-Authorized Certification Bodies ("ONC-

88. The fundamental difference between "testing" and "certification" is that "testing" is an objective data-dependent process while "certification" is more comprehensive and intended to consider other factors in determining whether an EHR meets the legal threshold for certified EHR:

> *To further clarify, we stated that a fundamental difference between testing and certification is that testing is intended to result in objective, unanalyzed data. In contrast, certification is expected to result in an overall assessment of the test results, consideration of their significance, and consideration of other factors to determine whether the prerequisites for certification have been achieved.*

HIT Temp Rule 36162-63.

89. To receive Incentive Payments, hospitals were required to own certified EHR technology that met the Health IT Standards Committee (HITSC) Final Rule standards. This is reflects the fact that the government's initiative was aimed at both hospitals, to meaningfully use EHRs, and to vendors, to create a robustly-functional EHR in the first place.



ACBs"). Since the outset of the Incentive Program, the ONC-AA has been the American National Standards Institute (ANSI). See https://www.healthit.gov/policy-researchers-implementers/permanent-certification-program-faqs#b2.

(https://www.healthit.gov/policy-researchers-implementers/about-onc-health-it-certification-program).

90. The Drummond Group ("Drummond"), a private corporation, has been accredited to perform testing and certification of EHR since the beginning of the Incentive Program.

91. The testing and certification standards administered by Drummond were set by federal law. Temporary certification standards were first published in the Federal Register on June 24, 2010 and permanent standards were published on January 7, 2011 and have been subsequently revised.[20]

92. Federal regulations allowed for the certification of an individual "Health IT Module," or for the certification of a "Complete EHR." 42 C.F.R. § 170.510.

93. For either certification, the process a software vendor had to follow was to arrange for a test date with an approved testing body (in McKesson's case, Drummond) and review the "scripts" that contained the specific functionality tests to be administered.

94. Vendors were permitted to clarify items with their testing body prior to the test date, and the certification test was administered remotely, via live teleconferencing.

C. The Marketplace For EHR After The Start Of The EHR Incentive Programs

95. The Medicare and Medicaid EHR Incentive Program acted as a catalyst in the marketplace for EHR by providing billions of dollars of financing to providers who purchased certified EHR.

96. The Incentive Payments are critical to hospitals and other providers since a new, complete EHR system may cost as much as $20 to $100 million. See Final Rule at 44549.

[20] See https://www.healthit.gov/policy-researchers-implementers/certification-programs-health-it; 75 Fed. Reg. 36158 (June 24, 2010) and 76 Fed. Reg. 1262 (Jan. 7, 2011).

97. However, Incentive Payments can be of such high aggregate amounts for a single hospital that they might cover a hospital's *total cost* of acquiring a certified EHR system. Final Rule at 44555-56.

98. In this way, government funds were effectively channeled from CMS, through hospitals, and ultimately to vendors of EHR like McKesson.

99. EHR vendors might choose to target relatively narrow workflows and create niche products without undertaking the massive development effort required to provide the bulk of workflows required by an entire enterprise. For example, a vendor might decide to develop and sell only an Emergency Department tracking board, or even just clinical documentation geared only toward Emergency Physicians.

100. Alternatively, a vendor might decide to provide the bulk of all of the EHR-based clinical workflows as a bundled suite of software components. This creates a much more robust product, with a much larger potential sale price, but also entails much greater developmental complexity, cost and risk.

101. A functional enterprise-wide EHR must have relatively seamless flow of information across disparate clinical workflows and settings with no loss of data integrity. Software used by clinicians in the enterprise must enable integration of information that is sourced in one setting to be available in a different setting so that a patient being taken care of in either place does not have their care compromised by inaccurate, incomplete or wrong information.

102. Single-vendor, enterprise-wide EHR suites require enormous resources for development, marketing, implementation and support. As a consequence, only a handful of large vendors have been able to compete in the single-vendor market for hospital-based enterprises needing an EHR.

In addition to McKesson, these vendors include Cerner, Meditech, Eclipsys, GE, Allscripts, Siemens, Epic and a few others with smaller market shares.

103. Under the guidelines of the Final Rule, a "complete EHR" is one which is able to provide all the functionalities of the individual components considered requisite for a minimal baseline suite of functionality, across the continuum of care for an entire patient encounter.

104. Beginning in early 2009, Meaningful Use certification and the standards which underlie the EHR Incentive Program became a de facto prerequisite for EHR components, because only the ownership of certified EHR qualifies a healthcare organization for incentive payments and avoidance of future penalties. Since that time, all major healthcare enterprises have determined that they will purchase only certified software meeting Federal standards under the EHR Incentive Program.

105. The procurement process for EHR is long and tedious. Some hospitals had to hire consultants to assist in selecting an EHR vendor and product. An important factor in this purchasing decision was the level of commitment by the EHR vendor to devote resources to working with that hospital and keeping its EHR products up-to-date over the long term. Other factors include an assurance from the vendor that the EHR will work as presented during sales and will deliver the foundational functionality the certification process outlines.

106. Hospitals that purchased EHR beginning in 2010 would universally seek to obtain Incentive Payments. Accordingly, a non-certified EHR simply would not be a viable product in the marketplace.

VI. FACTUAL ALLEGATIONS

107. In 1998, McKesson, at that time primarily a pharmaceutical distributor, acquired HBO & Company. This $14.5 billion acquisition brought McKesson into the market for EHR systems.

108. Over the next decade and thereafter, McKesson continued to add various EHR components to the base product suite it acquired with HBO & Company through acquisition of established niche vendors, bundling most of these components under the heading of the "Horizon Clinicals" suite.

109. By 2007, the Horizon Clinicals solution had a relatively full, but disjointed, product suite to offer. Under the Horizon Clinicals boilerplate were included products such as Star ADT, Nursing, Alerting, Meds Administration, Surgery, Emergency Department, Tracking Boards, Order Entry, Pharmacy, Radiology, Laboratory, and Record Archiving. Several products were acquired to add functionality for the Ambulatory (office visit) space with particular emphasis on Horizon Ambulatory Care, along with a product for the ambulatory equivalent of the inpatient registration system.

110. Examples of separately built products (most from external developers) that McKesson attempted to integrate by one means or another into a single-vendor suite include:

Horizon Care Alerts	Horizon Care Organizer	Horizon Expert Documentation
Horizon Expert Notes	Horizon Expert Orders	Horizon Order Management
Horizon Care Record	Horizon Emergency Care	Horizon Ambulatory Care
Horizon Admin-Rx	Horizon Meds Manager	Horizon Perinatal Care
Horizon Patient Folder	Horizon Surgical Manager	Horizon Lab
Horizon Enterprise Revenue Management	Horizon Emergency Tracking Board	Horizon Enterprise Visibility
Horizon Physician Portal	Horizon Cardiology	Horizon Radiology
Horizon Medical Imaging	Horizon Expert Plan	Horizon Anesthesia Management
Horizon Medication Reconciliation	Horizon Prescription Writer	Horizon Health Summary
Horizon Home Care	Horizon Intelligent Coding	

111. Prior to being sold within the Horizon Clinicals suite by McKesson, most software components themselves had been built by completely unrelated developers using different proprietary standards for data representation, different paradigms for clinical modeling, different mechanisms for inbound and outbound interfaces, and sometimes completely different

architectural layers using completely different database models such as Microsoft SQL or Oracle and Unix.

112. Because McKesson built the Horizon Clinicals suite largely by acquiring externally-developed components without effectively integrating them, each component retained its original user interface and internal structure.

113. However, every clinician faced problems from a lack of integration that reached far beyond the user graphical interfaces. Because critical data such as problems, medications, allergies and so on had to flow across and between settings, at any points where either the sourcing or display was improperly integrated, clinicians were left with questionable or missing patient information.

114. McKesson's Horizon Clinicals suite stitched together a wide variety of these independently-developed components. Many of them individually created sourcing and display mechanisms for the same dataset (for example, a problem or medication or allergy). However, McKesson was unable to integrate these duplicative functions in such a way that data integrity could be maintained across the continuum of its "complete EHR" since, when the suite was sold as a unit, the disparate datasets all competed or interfered with one another. As a result, a patient's medications or allergies entered into the "complete EHR" by one provider may not be visible to another provider for that same patient.

115. Consequently, McKesson's Horizon Clinicals "integrated suite" fundamentally suffered from the very problem that enterprises were trying to avoid when they bought a single-vendor solution: Critical clinical information that needed to be shared across the enterprise was in a format unique to each component and not sourced from a common central profile using a common standard within the suite.

116. This meant that data integrity was impossible to maintain, and patient safety was compromised. The entire suite became dysfunctional, with frequent breakdowns, widespread safety complaints, unacceptable backlogs for defect resolutions, and an inability to even track down root issues among all the competing branches of computer code for the various components. McKesson's sales process carefully hid these critical defects, of which it was aware, from all potential customers.

117. The Horizon Clinicals product sales team consisted of physicians, nurses, pharmacists and other clinicians, as well as administration and sales personnel. The prevailing belief of this team was that Horizon Clinicals suffered from substantial flaws that needed to be masked during sales presentations to customers in order to effect a sale, and McKesson gave the team specific instructions on how to do just that.

118. On multiple occasions Relator and the rest of the clinical presentation team received specific instructions from executive sales leadership – including Jim Jordan and Gerry McCarthy – to present the HC suite as more integrated than it was, more stable than it was, and more robust than it was. For example, Relator was told by Kendall Echols, a senior sales individual, on more than one occasion: "We (McKesson) never tell a customer we cannot do that function."

119. These issues were not mere kinks in the system – they went to the heart of the ability of Horizon Clinicals to perform its core function. Horizon Clinicals customers universally complained that their systems suffered from quality and safety defects so severe that nearly every customer has been forced to abandon and replace the software, and McKesson ultimately ceased the entire development of the product because it became impossible to support and maintain it.

120. Accordingly, McKesson leadership was well aware of the extent of these defects, and put in place mechanisms that made it difficult or impossible for customers to easily understand the

extent of the dysfunction. Key defects, including safety concerns, were not readily shared with outside parties. Customer lists were similarly not shared in order to prevent ready dissemination of complaints. Group customer meetings were managed as tightly as possible. Representations were made to customers that development fixes and major overhauls were pending even when development resources were being reduced. The primary consequence of this approach was to persuade customers to buy or maintain Horizon Clinicals even though it was known by McKesson to be fundamentally and irreparably flawed.

121. Relator had personal and direct experience with dozens of existing and prospective Horizon Clinicals customers while at McKesson. Examples include remote sessions for one or two customers/week over a period of six years, as well as site visits to existing or potential customers at, among other hospitals:

Baton Rouge General Medical Center	Bayhealth Medical Center, Inc.	Beebe Medical Center	Barnes Jewish Hospital	Botsford Hospital (MI)
Bronson Methodist Hospital	Cascade Valley Hospital (WA)	Catholic Health Systems	Chesapeake Hospital Authority	Covenant Health (TN)
Decatur Memorial Hospital	Eisenhower Medical Center	Elkhart General Hospital (IN)	Englewood Hosp. and Med. Ctr. (NJ)	Henry Ford Hospital (MI)
Genesis Healthcare Hospital (OH)	Grand River (Ontario)	Memorial Hospital at Gulfport (MS)	HCA hospital system	HealthAlliance Hospital (MA)
Heritage Hospital (NC)	Huntington Hospital (CA)	John Muir Medical Center (CA)	LA County + USC Medical Center	Lutheran Childrens' Hospital (IN)
Lancaster General Hospital (PA)	Longmount United Hospital (CO)	MacNeal Hospital (IL)	Mercy Hospital (IA)	Baptist Medical Center (MS)
Northwest Community Hospital (IL)	OhioHealth O'Bleness Memorial Hospital	Parrish Medical Center (FL)	Medical University of South Carolina	McLaren Port Huron (MI)

UnityPoint Health-Peoria	ProMedica Toledo Hospital	Providence Hospital (IL)	Roper Hospital (SC)	Sharon Hospital (CT)
Silver Cross Hospital (IL)	Hospital Solaris (DC)	MedStar Southern Maryland Hospital Center	Sparrow Hospital (MI)	St. Luke's University Health Network (PA)
Stormont Vail Health (KS)	Suburban Hospital (MD)	Southwest Medical Center (KS)	Tampa General Hospital (FL)	Tenet Healthcare System
ProMedica Toledo Hospital (OH)	Tucson Medical Center (AZ)	UHS	Vancouver General Hospital	Vanguard Health Systems
MedStar Washington Hospital Center (DC)	Wellmont Health System			

Relator is not aware of a single existing customer that was not frustrated with its Horizon Clinicals installation to the point of swapping out vendors, as each eventually learned that the functions Horizon Clinicals was certified for did not work as certified in real life. Relator's instructions from McKesson leadership were to assuage those concerns with reassurances that fixes were in the works even when the leadership knew they were not.

122. Ultimately, Horizon Clinicals failed in the marketplace because its flaws rendered it so profoundly dysfunctional and unsafe that existing customers rejected it and prospective customers refused to buy it. McKesson sold Horizon Clinicals as being certified by the government for foundational EHR functions while McKesson knew it was unable to execute those functions in a manner that supported real-world clinicians using a real-world installation of that product.

A. Target One: Drummond And False EHR Certification

123. The initial target of McKesson's fraudulent scheme was Drummond, the accredited certification body that would determine whether its Horizon Clinicals product was qualified to be a "certified" EHR. For the year 2010, McKesson sought "Complete EHR" certification for Horizon Clinicals. See 42 C.F.R. §§ 170.510, 545.

124. On information and belief, McKesson sought "Complete EHR" or certification of individual components of Horizon Clinicals from 2011 until the product was "sunsetted" in 2015.

125. This certification was both a legal and commercial prerequisite for Horizon Clinicals to be a viable complete EHR product for healthcare organizations to use under the Medicare and Medicaid guidelines for Incentive Payments.

126. McKesson knew in 2010 and thereafter that Horizon Clinicals did not meet the statutory requirements for a certified complete EHR, but was intent on obtaining certification quickly and by any means necessary. Drummond was one of the very first entities to be federally authorized to carry out testing and certification of EHR vendors, receiving such authorization on September 3, 2010. Like competing vendors, McKesson wasted no time applying to test for certification. McKesson was aware of the deep, persistent and ubiquitous concerns from its installed customer base that Horizon Clinicals was failing as an EHR. At the time of certification for Meaningful Use Stage 1 in 2010, McKesson could not point to a single customer out of hundreds of Horizon Clinicals installations as a referenceable site to demonstrate to prospective customers that the McKesson "complete EHR" Horizon Clinicals suite was capable of the basic EHR functions covered by the certification requirements.

127. To obtain certification, McKesson decided to exploit the fact that it knew ahead of time the specific functionality tests that Drummond would administer. It did so by designing a

modified and limited subset of software code customized to enable the Horizon Clinicals suite to pass the certification tests of functionality. McKesson was aware that real-world customers who installed a Horizon Clinicals suite in order to obtain the functions the modules tested for would be unable to replicate the certification workflows as they were presented to Drummond.

128. This was in part because customers would not have the kind of technical expertise and support required to create or maintain the specialized computing environment McKesson used for Horizon Clinicals certification.

129. Relator was the physician lead in 2010 on the McKesson team presenting Horizon Clinicals to Drummond for certification. He personally helped McKesson prepare the Horizon Clinicals testing environment against the National Institute of Standards and Technology (NIST) "scripts" created for the certification process, personally participated in practice sessions in advance of the test, and personally presented to Drummond the majority of the clinical portions of the scripts.

130. Subsequent to his role in the certification process, Relator was transferred to a strategist role reporting directly to Gerry McCarthy, SVP Product Management and Marketing, in Horizon Clinicals product development where he was able to more fully comprehend the deep divide between what he and others at McKesson had demonstrated to Drummond and what the practical experience was for customers who had purchased the Horizon Clinicals software.

131. As a member of the product development group, Relator learned that the Horizon Clinicals software used in the certification process was "artificial," meaning that it was specifically targeted to pass the MU1 certification scripts without correcting the fundamental flaws that kept Horizon Clinicals from actually delivering on the workflows contained within those scripts. It did not reflect what the experience would be for an actual clinician using an

installed iteration of the Horizon Clinicals suite, even for that particular individual function that was tested. For example, a real-world clinician managing a problem, medication or set of discharge workflows would not be able to do so the way McKesson presented it to Drummond. This would be the case even when a clinician was presented with the exact same workflows as were contained within a Drummond testing script.

132. Thus, even where a single component might be considered to pass a narrow certification step because software code tweaked for that script worked for that very narrow example, when combined into the Horizon Clinicals suite and sold as a "complete EHR," that function would break down across the continuum of care when the customer actually installed the software.

133. Indeed, McKesson maintained a development team in Alpharetta, GA, completely separate from the main Horizon Clinicals development group in Westminster, CO, which was charged by top management with reconfiguring the demonstration environment so that Horizon Clinicals could be certified. This team of highly trained specialists, referred to within McKesson as the "demonstration development team," could, and did, take software code from the main development group and altered it to minimize defects, customize functions, and otherwise manipulate the base code using expertise that would not be available to customers. This expert team evaluated the base code for errors and made sure the certification flows would avoid re-creating those errors. They were also able to create additional software such as custom-coded order forms which were not available to customers, but which could be presented to Drummond for the purpose of passing the certification. It was a lengthy and challenging process. The group devoted almost a full year to reconfiguring a Horizon Clinicals system so that it could successfully be used for certification purposes.

134. The modifications to the software code that were made by the "demonstration" development team were not included in the base commercial release of Horizon Clinicals sold to hospitals and could not practicably be replicated by those hospitals on their own. Nonetheless, the "demonstration" version of Horizon Clinicals was falsely presented to Drummond as the version that would be sold commercially as "certified" EHR.

135. For example, if the installed Horizon Clinicals suite had several patient or problem lists that were inconsistent or wrong, the certification presentation would use only one list to avoid exposing the flaw. This enabled Horizon Clinicals to fraudulently obtain certification for a particular workflow module even though in practice a customer would find that workflow to have critical errors.

136. McKesson held a number of pre-test meetings to make sure the model patients used for the certification tests were inputted into the system in precisely the manner necessary to conceal the fundamental flaws of Horizon Clinicals from Drummond. Where the software components that real-world clinicians had to use in everyday workflows were fatally flawed, McKesson devised means of avoiding them for purposes of obtaining the certification.

137. A key feature of Horizon Clinicals was a physician portal (HPP) that acted as the gateway for physicians to access the information contained in the EHR. Nearly 100% of Horizon Clinicals customers depended on HPP, which was always sold as part of the Horizon Clinicals software. But because HPP was so problematic, McKesson deliberately avoided using this core component during the certification testing even though it was in practice the primary way a physician would access the function the certification was designed to test. However, McKesson then presented Horizon Clinicals to customers by showcasing HPP for certain functions during demonstrations of the "fully certified" product.

138. Relator handled the Meaningful Use Stage 1 certification for Horizon Clinicals from a room in Alpharetta using McKesson's Alpharetta demonstration environment that contained the MU1 code from development (Horizon Clinicals 10.3.1.) as McKesson had reconfigured it, using carefully prepared patients, workflows, ordering forms and so on—all of which had been carefully tested against the specific Drummond testing method. Relator was accompanied during this certification process by three or four McKesson technical specialists, an RN clinician, a business analyst and multiple company executives. McKesson assigned an internal team to carefully inspect the NIST scripts and figure out which specific components of code could be used to pass the script; which should not be used; and which items needed to be specially coded by the demonstration team.

139. For example, the discharge workflow was effected by use of a custom-coded ordering form. As another example, when a "medication list" was pulled up, McKesson left out of its presentation that a medication begun in the Emergency Department would not appear in the inpatient setting. At certification, McKesson simply left key flaws like these out, and Drummond inferred from its presentation that the narrow, customized section of code McKesson created to display a medication list was the way the "complete EHR" functioned.

140. McKesson was thus fully aware that the full Horizon Clinicals software code for functions being tested did not work properly with respect to the certification criteria and chose to conceal this from Drummond and its customers. It was not even possible to separate out one of the certification-required "modules" because the Horizon Clinicals suite had not even been built that way. If the function the certification test module was evaluating had been presented the way it actually worked within a Horizon Clinicals installation, it would not have passed certification.

By hiding this from Drummond and from customers, McKesson was able to pass certification and fool customers into buying Horizon Clinicals as a suite of fully-certified modules.

141. The following paragraphs describe specific examples of how McKesson gamed Drummond's certification process by using modified software code during the certification tests that misrepresented the functionality that would be provided to customers in real-life situations.

142. Each of these examples addresses a federal requirement that is fundamental to the government's objective of having hospitals invest in and use EHR systems that promote more effective and efficient healthcare delivery. For example, allowing different providers to access a single patient's medication list at their respective points of care is foundational to providing proper treatment, and one of the core areas where electronic record systems provide a distinct advantage over paper records. Indeed, these examples are each derivative of the core set of 14 "meaningful use objectives" set forth in the Final Rule.

1. Requirement That Certified EHR Be Able To Record, Store, And Maintain A Patient's Active Medication List And Medical History

143. Federal regulations require that a certified EHR "[m]aintain [an] active medication list [, e]nable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care." 42 C.F.R. § 170.302(d).

144. The NIST testing script for this important, commonsense requirement involved a number of testing protocols designed to evaluate whether an EHR allowed a provider to record, modify, and retrieve patient medication lists within various care settings.

145. The Horizon Clinicals suite was so disjointed it was sometimes impossible for a clinician to even find the right patient to start with. A clinician would be presented with completely different patient lists because the supposed "common shared patient table" marketed to customers was a patently false misrepresentation.

146. Within the Horizon Clinicals suite, medication lists were sourced, maintained and visually presented in a wide variety of places—for example, the Pharmacy (HMM) workflow; the ordering (HEO) workflow; the patient history (HHS); the Emergency Department (HEC); physician views (HPP) and so on.

147. Flow of medication lists among all of these was highly complex and frequently resulted in errors for customers. McKesson therefore culled out only a small piece of workflow code, and falsely presented that at certification as the way medication lists were "recorded, modified and retrieved" throughout the system. In reality, real-world customers would not be able to access that type of medication list functionality with the Horizon Clinicals suite.

148. The Horizon Expert Orders ("HEO") user interface deployed for the Drummond certification process was only one mechanism out of many embedded in Horizon Clinicals where medication lists could be found and interacted with. But McKesson falsely presented HEO to Drummond as if it were "the" way its "Complete EHR" enabled the viewing and use of such lists using "the medication module." In point of fact no such "module" even existed and as with everything else, there were tables and schemes all over the place illustrating the disjointed effort to stitch together multiple, separately-developed systems.

149. Active medication lists could not be consistently viewed or managed for clinicians using Horizon Clinicals across the continuum of care for a full patient encounter. For example, a patient admitted from the Emergency Department ("ED") would typically have medications started in that department, but Horizon Clinicals did not show those medications to the nurse accepting the patient to a hospital bed even though that list of medications was critical to care of the patient.

150. Physicians and nurses faced even worse medication list dysfunction. When McKesson "integrated" the externally-developed HEO system into Horizon Clinicals, they were unable to bring the Emergency Department and the inpatient HEO modules together even though a typical hospital might get 50% or more of its patients through the Emergency Department.

151. Many patients admitted through the Emergency Department need to be seen by the inpatient doctor while those patients are still in the ED. Within Horizon Clinicals, inpatient physicians and nurses would not be able to see—or order—medications for that ED patient. On the other hand, if the patient status was electronically changed to "Inpatient" to enable care by Hospital clinicians while the patient was still in the ED, then the ED physicians and nurses would no longer be able to see (or order) medications.

152. McKesson's approach to this certification test was to present a single workflow for a model patient who was already admitted to the hospital as an inpatient. This approach allowed it to skip over the problems caused by faulty integration of the ED module.

153. For the certification, McKesson used a very limited workflow that showed an inpatient part of HEO, but avoided showing that clinicians actually using Horizon Clinicals would not be able to see the active medication list for a real-world patient moving throughout the various areas of care during her full encounter. McKesson was acutely aware of this critical flaw but was able to avoid exposing it to Drummond, thus fraudulently undermining the intent of the medication list script.

154. McKesson then represented its medication list "module" as "certified" even though it knew the way that function had been presented for certification by Drummond was not representative of the way it performed in the real world for customers having purchased the "complete EHR" Horizon Clinicals suite.

155. Analogous to the federal requirement for use of a medication list and history is 42 C.F.R. § 170.302(c) for recording, modifying and retrieving patient problems. For the certification process, McKesson presented HHS user interface code but in the real world, the product sold to hospitals did not even have a consistent mechanism by which to search for a problem to add in the first place. This fundamental flaw in Horizon Clinicals persisted even though the act of adding a new problem to a patient's record is the single most important function to assist a clinician in determining a patient's condition and treatment.

156. In summary, the code McKesson presented to Drummond for certification of the 170.302(d) requirement was materially different from the code that was sold to hospitals for use in the normal course of healthcare delivery. Customers using Horizon Clinicals would not have been able to address medication lists and medical history in a workable or reliable fashion for a typical patient who entered the hospital through the Emergency Department, a category that includes about 30-60% of all patients in a modern hospital.

2. Requirement That Certified EHR Be Able To Compare Two Or More Medication Lists

157. Federal regulations require that a certified EHR "[e]nable a user to electronically compare two or more medication lists. 42 C.F.R. § 170.302(j). The Final Rule, by way of example, highlighted the situation in which an externally provided medication list is compared to the current medication list in the EHR system.

158. The NIST testing "script" for this requirement required the EHR to simultaneously provide two separate medication lists for comparison.

159. For the Drummond certification, McKesson created two medication lists for comparison as required by the script.

160. To pass certification for comparing these two lists of medications, McKesson falsely presented the workflow to Drummond as representative of the way clinicians would use the software in practice. However in an actual installation, clinicians would need to access the medication comparison (and reconciliation) from a completely different part of the EHR system than was presented to Drummond, and from there would not be able to view the medication reconciliation module to compare the lists.

161. In point of fact, Horizon Clinicals physicians worked within their web-based Physician Portal, and the medication reconciliation tool was not even available through that portal for most physicians.

162. The capability of an EHR system to function as a cohesive unit goes to the heart of its utility. The certification scripts tested individual modules to make sure they were functional for that script. To achieve certification, McKesson mispresented a module as if it were representative of the tested function across the entire suite. In fact, upon receiving the whole Horizon Clinicals suite, customers would find the certified function non-viable in a real installation, because other necessary ways to access that functionality were broken or dysfunctional.

3. Requirement That Certified EHR Be Able To Identify Drug-Drug Interactions And Allergies

163. Federal regulations require that a certified EHR: "(1) Notifications. Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE). (2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks." 42 C.F.R. § 170.302(a).

164. Federal regulations further require that a certified EHR "[m]aintain active medication allergy list. Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care." 42 C.F.R. § 170.302(e).

165. The NIST testing "script" for this function required the EHR to automatically generate and indicate drug-drug and drug-allergy notifications.

166. It was well known within McKesson that Horizon Clinicals contained serious flaws which impeded the flow of allergy information among its various components.

167. For example, the pharmacy system (HMM) could not source allergies to the ordering system (HEO) thereby posing a significant risk that a patient would be prescribed a drug which would trigger an allergic reaction. In order to conceal this deficiency for purposes of the certification testing script, McKesson confined the allergy table to the Horizon Health Summary (HHS) module and then used HEO to present drug interactions even though in the case of an installed Horizon Clinicals suite, HEO would never see an allergy entered by a pharmacist.

168. As another example, the HEC emergency department software had its own way of presenting allergy reactions and histories (along with meds and problems and so on). McKesson simply directed hospital customers to only use the HEO-based workflows as if that were a viable solution when in fact it made the software completely disjointed and dysfunctional.

169. Customers using the delivered Horizon Clinicals suite would have to resort to a verbal or paper work-around for pharmacy-entered allergies, a critical source of error which put patient health at risk.

170. This paper or verbal "workaround" was the precise problem that EHR, and the government's EHR Incentive Programs were designed to solve. By concealing the fact that

hospitals would be forced to revert to paper and verbal communication because Horizon Clinicals was unable to perform core electronically-based functions, McKesson defrauded the government and undermined its policy objectives.

4. Requirement That Certified EHR Be Able To Record And Chart Vital Signs

171. Federal regulations require that a certified EHR: "Record and chart vital signs—(1) Vital signs. Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, height, weight, and blood pressure. (2) Calculate body mass index. Automatically calculate and display body mass index (BMI) based on a patient's height and weight. (3) Plot and display growth charts. Plot and electronically display, upon request, growth charts for patients 2-20 years old." 42 C.F.R. § 170.302(f).

172. The certification testing "script" for this function required the EHR to enter a patient's vital signs (height, weight, blood pressure) and allow those data to be accessed and modified correctly and without omission.

173. Horizon Expert Documentation ("HED") was only one of multiple modules in Horizon Clinicals that handled vital signs (VS). Since so many modules had been developed individually, and since vital signs are such an essential consideration in providing good medical care, each one of these modules typically had its own unique mechanism for presenting, storing and transmitting vital signs.

174. Horizon Clinicals thereby had many ways to deal with vital signs, but the disparate functionality spread across multiple modules created serious problems when a clinician needed to view these data in a real-life environment.

175. To pass certification, McKesson carefully and deliberately confined its demonstration to Drummond of vital signs functionality only to the HED module.

176. But, as McKesson well knew, a physician wishing to access a patient's vital signs at a hospital would typically use the Horizon Physician Portal (HPP), not HED. Physicians did not sign into HED and did not use HED screens since all of their workflows and information access had been designed to be done within the Portal, and HED was a completely foreign component to physicians.

177. However, the code McKesson included with the commercial version of Physician Portal had only a very limited capacity to display vital signs. Accordingly, McKesson took care to conceal this defect from Drummond and its customers.

178. Specifically, the display format for vital signs in the Physician Portal prevented the clinician from safely getting the full range of VS across the patient's encounter history to recognize patterns, trends or changes.

179. There were substantial customer complaints arising from this fundamental flaw that impeded the ability of hospitals to track vital signs based on anything beyond what was described as a "smattering of data" by one Horizon Clinicals customer, St. Luke's Health System, in 2011. Moreover, the customer recognized that this flaw posed a threat to patient safety:

> *I DO NOT HAVE THE ABILITY TO SHOW DR HOWELL 24 HOURS OF DATA IN FLOWSHEET FOR A PATIENT WITH MORE THAN A SMATTERING OF DATA.*
>
> *this issue is worth the caps. flowsheet has an artificial limitation that it will only render 14 columns of data, which means that i have NO ability to advise dr howell to use a foolproof setting that will never hide data for a day in a patient's stay….*
>
> *THERE IS A HIGH RISK OF A PATIENT SAFETY ISSUE DUE TO THIS TOOL's DESIGN. I can't say it any more plainly and directly than that…..*

180. This email from St. Luke's was written more than eight months after Tricia Hannig of McKesson had used an alternate section of code to achieve certification for Vital Signs from

Drummond. Furthermore, McKesson was aware of this limitation in Portal for years prior to certification.

181. Horizon Clinicals would not have passed certification for Vital Signs had McKesson not concealed from Drummond the limited functionality that was actually being delivered to customers.

5. Requirement That Certified EHR Be Able To Create An Electronic Copy Of A Patient's Discharge Summary

182. Federal regulations require that a certified EHR: "Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means." 42 C.F.R. § 170.306(d)(2).

183. For the discharge certification script, McKesson used HEO code written specifically by the Alpharetta division for the purpose of gaming the certification process.

184. This new code was necessary because, as McKesson realized, the actual Horizon Clinicals system would not have demonstrated the functionality required for certification. The solution McKesson used was to create specialized code for a very artificial sample discharge and then pretend that real-world customers could handle their discharges that way.

185. McKesson created for purposes of this certification test, a "discharge summary," which it presented to Drummond, containing examples of the kinds of information that a hospital might want their patient to receive at discharge.

186. Using this customized code, and presenting a dummy discharge summary, McKesson successfully deceived Drummond and thereby passed the certification test for this function.

187. In an actual installation, however, a customer would not have been provided with this specialized code nor with the ability to gather or display the required data as McKesson falsely

presented to Drummond it would. Nor did McKesson subsequently offer to customers an add-on software package to provide the functionality fraudulently presented to Drummond.

188. In effect, the entire discharge flow presented to Drummond for the purposes of passing the certification was a sham demonstration utilizing code created only for Drummond and was not representative in any way of how the actual software delivered to customers worked.

6. Requirement That Certified EHR Be Able To Maintain An Up-To-Date Problem List

189. Federal regulations require that a certified EHR: "Maintain up-to-date problem list. Enable a user to electronically record, modify, and retrieve a patient's problem list." 42 C.F.R. § 170.302 (c).

190. A patient's "problem list" is a list of present and past diagnoses that are relevant to the current care of the patient.[21] It is a core organizational tool, assisting clinicians in giving focused attention to managing individual medical problems during a course of treatment in multiple settings while simultaneously enabling them to better treat and consider the patient's needs as a whole.

191. The Emergency Department component of Horizon Clinicals was Horizon Emergency Care (HEC) which, like most other Horizon Clinicals modules, had originally been created by a third party vendor as a stand-alone system.

192. As such, HEC had its own original code for sourcing, storing, displaying and maintaining problems, allergies, and medications (PAM). Clinicians using HEC within the context of the entire Horizon Clinicals suite (*i.e.*, as part of a "complete EHR") would not have the ability to

[21] See https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/3_Maintain_Problem_ListEP.pdf.

use and interact with PAM the way McKesson fraudulently presented PAM-related modules at certification.

193. McKesson never rewrote HEC despite multiple promises to do so. McKesson also told customers that 70 developers were working on HEC instead of the seven to ten that were working on it. Since the true number of resources was so limited, McKesson chose to leave in all of the conflicting, confusing and redundant pathways to handle problems, allergies, and medications within HEC, making it impossible for physicians to get a clear idea of what was actually going on with a patient whose care involved the emergency department.

194. Consequently, Horizon Clinicals provided hospitals with neither clean, consistent views of PAM, nor with consistent approaches to retrieving and maintaining the data. Problems might show up one way if they left the HEC module to view HHS directly; another if they looked at prior information within old HEC code; another if they looked at problems within order flow, and so on—and none of these were a consistent or reliable view of the patient's problem list as required by the certification standard.

195. As another example, if treatment utilizing a critical medication was initiated in the Emergency Department, it would not flow over to the patient's medication list as seen by other clinicians throughout a hospital stay because of the inability of HEC to functionally communicate with the other modules of the "complete" EHR suite.

196. As a third example, if an attending clinician came to the Emergency Department to see a patient, that clinician would be unable even to write a prescription for that patient and communicate the existence of that prescription to the inpatient providers because the HEO ordering system for medications in the ED was not integrated with the inpatient systems into an operational whole.

197. Other examples include the inability to exchange allergies between the pharmacy module and the rest of the suite. Likewise, orders could not properly be exchanged between HEO (Horizon Expert Orders, the main ordering clinical tool). Another example of a design deficiency that prevented Horizon Clinicals from maintaining a reliable problem list was its inability to communicate properly with its supposedly integrated modules, the HOM (Horizon Order Management) module in particular.

198. McKesson knew that Horizon Clinicals' integration with respect to problem lists was not functional. Julie Heitz, the person in charge of development for Horizon Ambulatory Care, stated in an email after one critical integration failure: "As we continue to move down an 'integrated' path – I hope we can learn from this disaster and take a much more rigid stance on how apps MUST [be] integrated to an enterprise table."

199. Ms. Heitz's comment was made nearly a year after McKesson fraudulently obtained Horizon Clinicals' Meaningful Use Stage One certification, reflecting the fact that McKesson was nowhere near solving the issues around its need for integration and rewrites. Yet at certification it presented its PAM modules, along with all the other certification criteria, as being properly coded so they were fully functional for end users who bought the complete EHR suite.

200. McKesson did not allocate resources to create certification code and fix code the customers would actually use. Instead, it simply created certification-specific code, let all the broken code remain in place, and then proceeded to mislead Drummond by gaming the certification examination and thereafter the hospital market by presenting the entire Horizon Clinicals package to hospitals as "certified" code.

201. Unaware of McKesson's scheme, and in good faith, on or about November 19, 2010 , Drummond certified Horizon Clinicals as a "complete EHR" capable of satisfying federal Stage 1 Meaningful Use standards.

B. Target Two: Hospitals And False Marketing

202. Achieving certification as a complete EHR was an essential predicate to marketing Horizon Clinicals to hospitals. This gave Horizon Clinicals the appearance of possessing a level of government-endorsed functionality that it did not in fact possess. Without it, there was simply no market. Thus, insofar as that certification came about as a consequence of McKesson's deliberate fraud, it necessarily tainted as fraudulent each sale of Horizon Clinicals.

203. McKesson's fraudulent marketing of Horizon Clinicals went beyond the fraudulently obtained certification, however, permeating its entire sales strategy. The essential themes of the Horizon Clinicals sales pitch were developed by McKesson's Marketing Department, with input from individual Product Managers. Those taking part in the sales presentation process were put through rigorous internal training at McKesson before the company allowed them to present to potential customers.

204. Most McKesson sales presentations for Horizon Clinicals involved a "live demonstration" of the product, because hospitals understandably desired to observe how the system worked in practice.

205. McKesson fundamentally misrepresented Horizon Clinicals' functionality in order to reassure potential and actual customers that Horizon Clinicals would enable them to achieve full compliance with the Meaningful Use initiatives and standards established by the Medicare and Medicaid EHR Incentive Programs. McKesson knew that the only way to successfully sell Horizon Clinicals was to create deliberately false presentations so that the flaws would remain hidden.

206. False statements included:

(a) That Horizon Clinicals met the legal standards for a "certified" complete EHR and could be used by hospitals to meet Meaningful Use criteria for Medicare and Medicaid Incentive Programs, and that Horizon Clinicals would enable clinicians to safely and efficiently take care of patients using the core workflows that had been established as foundational elements for an EHR by the government's certification program.

(b) That McKesson had and would devote all necessary resources to ensure that customers would receive a product that worked as presented during software demonstrations, and that Horizon Clinicals was and would remain a premier product that can be counted on for the long haul.

(c) That Horizon Clinicals is a unified, "complete" Electronic Health Record so that customers do not have to worry about information flow across the enterprise or between Horizon Clinicals applications.

(d) That the "live demonstration" scenarios presented software (often referred to as COTS for commercial off-the-shelf software) that would work for customers when installed in the same manner it was presented.

(e) That McKesson uses a "single database" approach in which a given category of data such as a medication or allergy list is stored with a single set of tables devoted to that function so that data integrity would always be maintained as a patient moved throughout a clinical encounter.

207. McKesson masked or otherwise hid flaws that the typical hospital customer would view as a deal-breaker because those flaws would disrupt and impede clinical care, adversely impact patient safety and generally undermine clinician satisfaction.

208. For example, in a January 28, 2011 email from McKesson Client Executive Michael Marcus, Mr. Marcus directed a full marketing team in preparation for the North Oaks Health System Diagnostic Center. He instructed that "[i]t's also important to remember what not to say," which included "[s]tay away from interfaced and fully integrated conversations."

209. Indeed, customers asked McKesson, "if your system is integrated, why do you need a portal?" Customers noticed that the Physician Portal was a web-based scheme to provide an appearance of integration but wondered why it would be necessary to add that extra shell if, in fact, the underlying components were already integrated. The truth was that McKesson had never executed their promise to re-write the various components into an integrated whole, despite telling customers (including Relator's home enterprise) that this would be done. McKesson could only hide this fact by making display-based shells such as Physician Portal and Common Application Framework (CAF) that gave a false appearance of integration.

210. McKesson forced its sales and marketing teams to repeat the false statement that Horizon Clinicals utilized a "single database" for patient information. Indeed, training sessions for the marketing team emphasized that this was a key customer-facing message. But it was a message that was patently false. Horizon Clinicals did not rely on a single database but instead was an unworkable conglomerate of many previously-independent modules that used different databases to store, access, and modify patient information.

211. Nonetheless, McKesson marketed Horizon Clinicals as having a single database, or "instance," of critical patient information such as allergies and medications. In a presentation

given at the Health Information and Management Systems Society Annual Conference & Exhibition in 2011, McKesson described its "Enterprise Data Model" as having "a single storage location" for allergies and medications that was shared by its various applications.

212. Relator moved from McKesson's Horizon Clinicals sales team to a development role in 2011 because he confronted McKesson leadership with the profound deficiencies and told executives he was no longer willing or able to sell Horizon Clinicals under false pretenses. In that development capacity, he learned that the chasm between how Horizon Clinicals was marketed and the true functionality of the product being delivered was far greater than he previously understood.

213. But the message that McKesson would use its vast resources to put necessary money into Horizon Clinicals for the sake of the customers who bought it turned out to be as false as many of the other more specific messages around product functionality.

214. A specific example of deceptive messaging around McKesson's supposed unlimited commitment to a particular product involves the Advanced Dosing component of Horizon Expert Orders (HEO). Advanced Dosing had been developed internally by Duke University, and McKesson acquired it to be sold as an add-on to HEO within the Horizon Clinicals suite.

215. Advanced Dosing was a very attractive offering in principle because its purpose was to enable safer computerized ordering for patients with very complex problems such as renal disease. As such, it helped to generate interest in Horizon Clinicals.

216. Potential customers were very impressed with the product features as marketed by McKesson. In order to drive sales, McKesson sales executives would explain that Advanced Dosing was up and running at Duke University and that other customers had purchased the product – what McKesson knowingly did not reveal, however, and what was critical, was that

Duke was the only hospital where the Advanced Dosing software had successfully been installed. None of the other customers who had purchased the product had been successful in getting this flawed product to work.

217. This false marketing was intended to, and did, mislead customers to believe that Horizon Clinicals was on the cutting edge of computerized physician order entry, and that the functionality McKesson could deliver was ahead of its competitors. Advanced Dosing drove HEO as a product, and HEO was in turn a driver in selling the entire Horizon Clinicals suite.

218. McKesson sold the Advanced Dosing product to about 30 customers, with each sale being used as a reassurance to the next buyer that Advanced Dosing was an important component rapidly gaining acceptance in the marketplace.

219. In reality, Advanced Dosing was a "ghost product," which never achieved functionality within the Horizon Clinicals suite. Customers who bought Advanced Dosing simply never received any benefit from it at all, as no one at McKesson even knew how to install it.

220. These false marketing messages were not the actions of rogue employees. They were delivered to customers by high-ranking (SVP-level and above) executives from McKesson to make sure they resonated, and to make sure the customer was aware that support for the product came from the highest levels within McKesson.

221. For larger or key deals, it was common to bring hospital system decision-makers by private jet to Alpharetta and put them in front of senior executives–including the Division Presidents–to further engender trust and confidence in McKesson's sales presentation. In point of fact, at most sales encounters with larger customers, the sales executives did all the talking with the exception of the demonstration presentation itself. In many instances, McKesson clinicians were discouraged or outright prohibited from even speaking informally to clinician

customers. Sales executives deliberately discouraged off-script workflow demonstrations, and severely reprimanded clinicians who went off-script or spoke frankly and honestly about product limitations.

222. For instance, at one typical demonstration for Englewood Hospital and Medical Center, Horizon Expert Notes, Relator answered a clinician who had some objections about product deficiencies. Relator said that he agreed with the clinician, but hoped McKesson would be able to improve that type of functionality in the future. After the demonstration, Relator was taken aside by the sales executive, Kendall Echols, and scolded for being so frank and risking the sale.

223. On multiple occasions, another McKesson sales clinician, Tricia Hannig, was berated by a McKesson sales executive because she admitted to too many product deficiencies when challenged by customers in the audience. After being criticized by Kendall Echols at a Suburban Hospital demonstration for not presenting the software positively enough, Ms. Hannig broke down sobbing. (Ms. Hannig was a highly-regarded nurse clinician who was given an award for being a Sales Consultant of the Year.) Kendall Echols said directly to Relator, "McKesson wants me in the loop for big deals because I always win the deal." Mr. Echols frequently misrepresented Horizon Clinicals as being far more robust, stable, and functional than it was during conversations with customers.

224. After another demonstration, Relator and another clinician, Robert Peed, were directed to be less than honest by a different sales executive, Todd Karner, who reminded them "We NEVER say no. We NEVER say the product does not have that functionality. We do not tell customers we cannot do something."

225. McKesson's fraudulent marketing was initially very successful. McKesson reassured existing unhappy customers that the new release of Horizon Clinicals was foundationally sound,

as proved by the certification. New customers were told this was a completely new version, and that they did not have to worry about past issues prior customers had had with Horizon Clinicals.

226. However, inevitably hospitals soon began encountering multiple intractable problems utilizing Horizon Clinicals as McKesson had represented it would function and they began lodging complaints with McKesson. Relator spent the majority of his customer-facing time addressing those complaints. Based on discussions with his fellow McKesson peers and leadership, Relator came to believe the safety and performance issues with Horizon Clinicals were universal across the entire spectrum of customers.

227. While preparing for the Meaningful Use Stage 1 process, Relator obtained a McKesson spreadsheet that indicated nearly 600 backlogged defects. These defects were assigned by McKesson "severity rankings" that were intended to represent a range of criticality from minor to commercially fatal.

228. Fifteen of the almost 600 defects identified on this spreadsheet were marked Severity 2 – indicating a degree of severity requiring immediate repair.

229. There was intense internal pressure to downgrade the "severity" of defects so as to not interfere with Horizon Clinicals' sales. Even so, many backlogged defects remained on the list for months or years, and there were many defects beyond the ones indicated on that spreadsheet.

230. The actual Horizon Clinicals product was incapable of providing the functionality represented at sales pitches. Indeed, the lack of a single database and the inability of the various modules to freely and reliably exchange and incorporate information rendered HC unworkable. Most customers recognized that given the system's rampant shortcomings, patient safety was necessarily being compromised. Customers ultimately concluded Horizon Clinicals would not be a viable long-term EHR solution despite the millions of dollars they had invested (much of

which came directly from the federal government in the form of Incentive Payments), and the enormous expenditure of effort in choosing the right EHR vendor.

231. Relator was not alone among McKesson employees in understanding that the company's marketing did not accurately represent its products. Cynicism about McKesson's sales methods and fraudulent representation extended throughout the clinical demonstration team and even to the highest-ranking executives themselves. Gerry McCarthy, then in charge of Horizon Clinicals development, responded to Relator's objection that McKesson's statements to customers about Horizon Connect were completely false with a confession: "I sell a little piece of my soul every time I talk to a customer."

232. Ultimately Horizon Clinicals failed in the marketplace, and every customer has had to discard their entire investment in the product. And the size of that investment was significant. For instance, Englewood Hospital in Englewood New Jersey, a representative hospital customer, was quoted an initial one time cost of over $16 million for a complete suite of required applications and over $1.2 million in annual fees.

C. Target Three: The Government And EHR Incentive Payments

233. Through the Medicare and Medicaid Incentive Programs, the government became a source of billions of dollars of funding for EHR technology.

234. The funds received by hospitals in the form of Incentive Payments were effectively passed along to EHR manufacturers such as McKesson as payment for the sale of purportedly certified EHR.

235. Accordingly, the ultimate target of McKesson's fraudulent scheme was the government, whose Incentive Payments were necessary for its fraud to succeed.

236. This was confirmed in a September 2, 2011 email from David Nassim, M.D. (VP Medical Affairs), that told Relator "the focus has to be on getting Eisenhower [hospital] live [with Horizon Clinicals] because they need to qualify for ARRA." (Emphasis added.)

237. Claims by hospitals for Incentive Payments from Medicare and Medicaid were false because technology did not meet statutory standards and was not in fact "certified EHR."

238. Claims by hospitals for Incentive Payments from Medicare and Medicaid were also false because they attested to "meaningful use" of a certified EHR.

239. The required attestations for requests for Medicare Incentive Payments are made electronically through the Medicare & Medicaid EHR Incentive Program Registration and Attestation System.[22]

240. Hospitals must provide in their EHR Incentive Program Attestation the EHR Certification Number of their certified EHR system.[23]

241. Hospitals must also provide in their EHR Incentive Program Attestation the Meaningful Use Core and Menu Objectives it has attained.[24]

242. This attestation represents that during the applicable reporting period, the hospital in fact satisfied the requirements for Incentive Payments. 42 C.F.R. § 495.8(b)(1)(i) (*Attestation ... that*

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[22] "Attestation User Guide," Centers for Medicare & Medicaid Services (Dec. 2015), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/UserGuide_EHAttestationUserGuide2015_2017.pdf.

[23] "Attestation User Guide," Centers for Medicare & Medicaid Services, at 11 (Dec. 2015), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/UserGuide_EHAttestationUserGuide2015_2017.pdf.

[24] "Attestation User Guide," Centers for Medicare & Medicaid Services, at 12 (Dec. 2015), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/UserGuide_EHAttestationUserGuide2015_2017.pdf.

during the EHR reporting period, the eligible hospital or CAH used certified EHR and specify the technology used[, and] Satisfied the required objectives and associated measures under §495.6(f) and §495.6(g).)

243. Electronic signatures on behalf of hospitals certify to the following:

> *I certify that the following information is true, accurate, and complete. I understand that the Medicare EHR Incentive Program payment I requested will be paid from Federal funds, that by filing this attestation I am submitting a claim for Federal funds, and that the use of any false claims, statements, or documents, or the concealment of a material fact used to obtain a Medicare EHR Incentive Program payment, may be prosecuted under applicable Federal or State criminal laws and may also be subject to civil penalties.*[25]

244. Hospitals seeking Medicaid Incentive Payments must submit a statement that is signed by the provider and contains the language: "*This is to certify that the foregoing information is true, accurate, and complete. I understand that Medicaid EHR incentive payments submitted under this provider number will be from Federal funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws*." 42 C.F.R. § 495.368(b).

245. These certifications play an important role in the EHR Incentive Program because the information that is self-reported by providers on claims for EHR Incentive Payments is not independently verified for accuracy by CMS prior to payment.[26]

246. The fatal flaws inherent in the Horizon Clinicals product detailed herein also caused hospital customers to submit claims for healthcare services to Medicare and Medicaid that were false because they were miscoded and/or not reasonable and necessary.

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[25] "Attestation User Guide," Centers for Medicare & Medicaid Services, at 67 (Dec. 2015), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/UserGuide_EHAttestationUserGuide2015_2017.pdf.

[26] See "Early Assessment Finds That CMS Faces Obstacles In Overseeing The Medicare EHR Incentive Program," Dept. of Health and Human Services, Office of Inspector General (Nov. 2012).

247. Ultimately, the Horizon Clinicals customers themselves demonstrated how profoundly flawed the system was. Hospitals uniformly and universally revolted, rejecting Horizon Clinicals as a viable EHR.

VII. SCIENTER

A. Internal Discussions

248. Executive leadership at McKesson was aware of severe product flaws but continued to knowingly market Horizon Clinicals in a manner that misrepresented the functionality and legal status of Horizon Clinicals to customers. Relator personally presented to top McKesson executive leadership critical shortcomings and consequent safety/performance flaws on numerous occasions. During those conversations McKesson leadership acknowledged the existence of these flaws.

249. Indeed, the entire sales and marketing process at McKesson was carefully staged to ensure the hospital customer or potential customer never understood the inherent limitations in Horizon Clinical's patchwork design.

250. New employees whose positions necessarily would entail speaking directly to customers or potential customers had to complete an internal McKesson training program designed to instill the false messaging that lay at the heart of McKesson's sales pitch.

251. A new clinical hire was given a trial period to learn the Horizon Clinicals software and messages, and how to present in front of an audience. Their longer term employment was conditioned on this trial period, and if they were hired as permanent sales clinicians, they then had to pass the more formal "sales certification" process.

252. A sales team typically consisted of both marketing and clinical personnel. However, it was McKesson's approach to have the marketing personnel respond to challenging questions at sales pitches because they had been carefully instructed on concealing flaws and staying on

message. McKesson's clinician team members would be reprimanded if they responded to a probing customer question in a fully honest way.

253. It was the "sales certification" process that first exposed Relator to the extent to which McKesson sales and marketing was willing to misrepresent Horizon Clinicals in order to drive a sale. Prior to his employment with McKesson, Relator had extensive experience already with the 7.X and prior releases of Horizon Clinicals, and thus he already knew what the deficiencies were for many of the components.

254. Relator was motivated to join McKesson to use his clinical experience to help the company correct the more serious design and operational flaws in its EHR products. Over time, however, it became evident to Relator that the main reason McKesson hired clinicians for sales roles was not for their input into software improvement but instead to falsely convey the message that Horizon Clinicals worked for clinicians in real life situations. In that regard, the entire internal clinician certification process was geared toward making sure Sales Clinicians drove key messages and hid flaws from the customers.

255. Relator came to learn that it was a career-ending move in McKesson's sales department to be honest with customers about the flaws in Horizon Clinicals. During the internal "sales certification" process, the first step was to have the clinician master the basic sales messages whether or not they were accurate. Because he was outspoken and honest about the fundamental flaws in Horizon Clinicals and the fraudulent misrepresentations to customers, McKesson marginalized Relator and eventually discharged him from the company, despite having awarded him Sales Consultant of the Year during the period when he was presenting Horizon Clinicals as McKesson wanted it presented.

256. For example, during initial testing to determine if Relator would be permitted to join the HC sales force, the single most important message McKesson drove home and the key concept that the sale force had to communicate, was that McKesson was now a "single database" suite. Cerner and Epic were major competitors at the time, and they had "single databases" at their core, unlike McKesson. The company line was considered absolutely critical – though patently false – and if the clinician did not get it right he or she would not be allowed to sell Horizon Clinicals.

257. For software glitches, which were pervasive during sales demonstrations (even though McKesson was using its own tightly-controlled remote environment), the sales team simply blamed the "internet connection" when the software locked up and became temporarily unresponsive or required a complete reboot.

258. Such software "hangs" were common for customers when using the software in real-world situations, so this was an important hurdle for the sales team to overcome. It was a standing joke among the sales employees that the handiest phrase was "My internet is really slow today." Indeed, this is one of the first "skills" any new recruit needed to pick up, since as new users, they were at greatest risk for inadvertently trying to use a function in the demonstration that would cause Horizon Clinicals to "hang."

259. Relator learned these lessons first-hand. He was taken aside by Kendall Echols at a large sales presentation after agreeing with an physician in the audience that the software should be able to do something that it could not. Relator was severely admonished for his honesty, and Mr. Echols told him that: "I (Kendall) never lose a big deal; that's why they give them to me," and "we never tell customers—never, never—that we cannot do something clinicians want the software to do."

260. During 2009 and 2010, Relator personally attended multiple internal planning meetings on how to approach the EHR certification dilemma. Present at those meetings were product managers and sales management. The company knew it was essential that Horizon Clinicals be certified by Drummond as quickly as possible, but also recognized that it did not presently possess the functionality necessary to achieve the certification. The decision made from the highest levels of McKesson leadership to those developing Horizon Clinicals was unequivocal: McKesson must certify the product as a Complete EHR, and must prioritize all software development so that the MU1 certification scripts could be met with tweaked code (versus rewrites for a whole function) instead of putting resources into developing and integrating the code that customers would need to actually achieve the level of functionality with Horizon Clinicals that Drummond was testing for.

261. Accordingly, the Horizon Clinicals software was tweaked to contain code specifically designed to pass the certification scripts. Inexcusably, McKesson never disclosed or addressed the fact that the functionality McKesson demonstrated to Drummond was a mirage – the system appeared to work but as actually configured, it did not. And the software tweaks performed on the particular Horizon Clinicals version used for the certification did nothing to correct the conglomeration of defects plaguing the version that hospitals would be purchasing.

262. The plan McKesson executed was to deliver to customers both the tweaked code from the certification tests, plus code that could not pass those tests but which customers needed for practical application of the EHR, and then sell the complete Horizon Clinicals as a certified EHR.

B. Customer and Potential Customer Complaints

263. On Nov. 2, 2009, a Territory Vice President (Stephen Kopech) emailed a large group of McKesson employees to report on the concerns raised about Horizon Clinicals by Baton Rouge

General Medical Center. These concerns included, "Impact to pt safety due to lack of integration: no way to follow the administration of sedatives from ED to various in-patient settings"; and "Dr. Robert's stated that this issue [duplicate medical record and encounter numbers] continues to plague BRG and creates workflow barriers as well as pt. safety risks."

264. In sum, "Many expressed disappointment that the level of integration promised in the original process was never delivered upon."

265. Concerns about McKesson's lack of integration were echoed in June 2010 by Northwest Community Hospital, IL, which informed a team from McKesson that "I will tell you that there are major concerns about the lack of integration of data between HEC and HED."

266. In July 2011, John Muir Hospital, Walnut Creek, CA lodged a list of complaints with McKesson. Among them were: multiple admitting systems that need to be integrated, multiple scheduling systems, no common tables or database between applications, and that each application requires its own "foot-print," or underlying operating system.

267. In August 2011, McKesson was struggling to respond to a hospital customer, Eisenhower Medical in Palm Springs, CA, which was "upset about our 'lack' of solid integration of [medications] between HAC/EPW/HSM and HHS." In an internal email, it was noted that Eisenhower had complained that in some instances, Horizon Clinicals would show different doses for the same patient medication, and in other instances not show correct dose or medication strength information at all.

268. These and other customer complaints were material to Drummond's decision to certify Horizon Clinicals and to the government's decision to make EHR Incentive Payments to Horizon Clinicals users – a fact McKesson had every reason to know. The "EHR Testing and Certification Guide" published by Drummond on August 31, 2010 made this fact clear by stating

that customer complaints must be promptly provided to Drummond because "this information is important to [Drummond] and to ONC." Additionally, the form letter that Drummond sent to EHR vendors informing them that their product had successfully obtained certification contained the following ongoing requirement:

> Drummond Group requires that your company keep a record of all complaints made known to your company that relate to your product's compliance with the criteria set forth by the HHS Secretary and the resulting certification by Drummond Group. We require that you provide these complaints to us as you receive them. This information is important to us and to ONC. All complaints will become part of our due diligence for continued process improvement to improve Drummond Group's process and will be forwarded on to ONC to ensure the overall confidence in the ONC-ATCB Program.

269. On information and belief, McKesson did not comply with this express requirement to promptly notify Drummond of all customer complaints directed to McKesson that relate to Horizon Clinicals' compliance with the government's certification criteria.

C. Relator's Complaints Up The Corporate Ladder

270. McKesson passed the Drummond certification tests by using the Physician Portal for "selecting a patient," but in the real world a customer would be given an entirely different patient list if they made the request through another aspect of the software.

271. McKesson had no intention of letting Drummond know that patient lists were not synchronized within the full code actually given to customers for the fundamental task of selecting a patient.

272. Relator knew that the representations McKesson made to customers to induce them to buy Horizon Clinicals ranged from deceptive to fraud at a most fundamental level. He expressed these concerns openly and repeatedly all the way up the management chain, including to John Hammergren, then (and still) CEO of McKesson Corporation.

273. When Relator's concerns were not acted upon by sales executives and leadership, he sought and obtained a transfer to the development group, where he gained added perspective on just how wide the divergence was between what McKesson was telling customers and what was actually true.

274. Relator personally ensured that the McKesson leadership knew specifically what kind of issues its customers were facing, and the pervasive failure of McKesson to address them. Relator had discussions from 2009 through 2013 with his immediate physician supervisors, the executive chain for MPT (McKesson Provider Technologies) in Alpharetta GA, the development leadership in Westminster, CO (who reported to Alpharetta), and eventually CEO John Hammergren.

275. Those leaders included the MPT President Dave Souerwine, as well as high-ranking executives such as Rod O'Reilly, Jeremy Chandler, Gerry McCarthy and Marcy Tatsch.

276. In 2009, at McKesson's annual banquet where Relator received the Solutions Group Consultant of the Year award, John Hammergren invited Relator to make any comments he had to him directly.

277. Relator took him up on that offer and on May 11, 2009 sent a letter along with a summary of some of the technical and marketing challenges facing Horizon Clinicals. Hammergren called Relator for a follow-up conversation, and subsequently Relator travelled to McKesson headquarters in San Francisco to speak with Randy Spratt, CIO of McKesson. The letter contained the following statements which highlighted the lack of a common platform, multiplicity of computer "bugs, and the failure to integrate the outpatient setting with inpatient care:

- *The most pressing problem facing Horizon Clinicals is the lack of an overall framework. There is no clear vision of how the complete health record should look and work.*

- *It is a common perception among McKesson clientele that while annual roadmaps promise future integration and elimination of silos, the delivery of that promise remains perennially unfulfilled.*

- *The most fundamental reason for both the overall complexity of underlying code and the difficulty delivering bug-free high-performance code is that there is no common platform.*

- *Most core applications are minimally different from when they were acquired, even when they have been part of the Clinicals suite for many years. Ambulatory, Emergency Care, Surgery and Order Entry are just a few examples of applications virtually indistinguishable from their originals acquired years ago. While all have had enhancements, none have been brought from discrete, separate applications into a common health record paradigm, and none have even had the core user workflow interface changed to a common look and feel.*

- *Most potential customers want to see "everything" working, and the vast majority of clinicians using, in a single location. McKesson does not have <u>even one</u> such comprehensive site, particularly if the criteria are added that physicians must be robustly using the full clinical suite including physician documentation, and the outpatient arena must be tightly integrated with the inpatient arena where the patients are part of a common enterprise. Considering that we have approximately 150 "M"-class customers, this is a remarkable commentary on how effectively the sales team has been able to sell without any proof that the end-product is deliverable.*

278. Relator's letter to McKesson's CEO also included the following, prescient warning:

Perhaps the biggest challenge on the near-term horizon is the ARRA "stimulus" incentive.

279. Relator personally presented his serious concerns regarding Horizon Clinicals to McKesson's MPT President Dave Souerwine, as well as to Gerry McCarthy and Rod O'Reilly, who were the executives in charge of software development. Relator demonstrated that the software would generate one patient list when requested through the Physician Portal and a <u>different</u> patient list when requested through the CAF. This meant that the exact same user in the exact same session wanting the exact same function--his patient list--would get two completely

separate results. Using what McKesson marketed as "certified" software, a clinician would not even be able to find the right patient to take care of.

280. Relator pointed out numerous other similar flaws, and pointed out that for a typical patient scenario, "We own every piece of software we need for this scenario, and we have owned them for at least 5 years. None of our customers could take care of this patient. We would be unable to even demonstrate this scenario today without mocking up one-off patches that do not really exist."

281. Gerry McCarthy responded to Relator's concerns by berating him for "putting this out there."

282. On October 25, 2010, less than four weeks before McKesson obtained certification for Horizon Clinicals, Relator emailed Mr. Souerwine and detailed a number of intractable design and operational failures plaguing the Horizon Clinical product:

- *The current initiatives perpetuate exactly the weakest point of McKesson software: We have disjointed pieces (with the same McKesson boilerplate, from a customer standpoint) being created in multiple duplicative silos across multiple business units reporting to multiple leaders. We are doing this right now. A first example would be clinical documentation. Right now we have programmers at OnMark, Fusion, Practice Partner, Paragon Emergency Care, Paragon Nursing, Paragon Physician Documentation, Horizon Ambulatory Care, Horizon Emergency Care, Horizon Perinatal Care, Horizon Expert Documentation, Horizon Anesthesia Care, Horizon Expert Notes and Relay (and probably others) all addressing the exact same function: "How does a clinician enter a point of history or a physical finding on her patient?"*

- *A second example would be how we answer the simple question: "Where is my patient, and what is going on with him?" Worse, lacking among their primary objectives is the concept of designing into some sort of larger whole EHR structure. They are designing to their narrow requirements, often with no idea of what the next group over is doing.*

- *No amount of operational improvement, smarter programming or better testing can create an efficient machine when the level of effort is directed at the individual components of a Rube Goldberg design. What you would end up with is a perfectly-functioning, expensive and complicated machine which is impossible to evolve and improve because there is no overall design—there are only individual components cobbled together. That overall design is our greatest challenge.*

VIII. COUNTS

COUNT I: FALSE OR FRAUDULENT CLAIMS
Federal False Claims Act
31 U.S.C. § 3729(a)(1)(A)

283. Relator repeats and re-alleges the preceding paragraphs as if fully set forth herein.

284. Defendant knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

285. Such actions were done knowingly, as that term is defined in 31 U.S.C. § 3729(b)(1).

286. Because of Defendant's acts, the United States has sustained damages in an amount to be determined at trial and therefore is entitled to treble damages under the False Claims Act plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

COUNT II: FALSE STATEMENTS
Federal False Claims Act
31 U.S.C. § 3729(a)(1)(B)

287. Relator repeats and re-alleges the preceding paragraphs as if fully set forth herein.

288. Defendant knowingly made or used, or caused to be made or used a false record or statement material to a false or fraudulent claim in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

289. Such actions were done knowingly, as that term is defined in 31 U.S.C. § 3729(b)(1).

290. Because of Defendant's acts, the United States has sustained damages in an amount to be determined at trial and therefore is entitled to treble damages under the False Claims Act plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

VIII. PRAYER FOR RELIEF

291. WHEREFORE, Relator James Thompson respectfully requests that this Honorable Court enter judgment in his favor and in favor of the United States of America and against Defendant as follows:

A. For the United States, treble damages and civil penalties of not less than $5,500 nor more than $11,000 per false claim pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(1);

B. For pre-judgment interest on all damages awarded;

C. For any and all reasonable costs, expenses and attorneys' fees;

D. For an award to Relator in the maximum amount permissible under law; and

F. For such other and further relief as the Court deems just and equitable.

IX. DEMAND FOR JURY TRIAL

292. A jury trial is demanded in this case.

July 13, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have caused a copy of the above Complaint to be served on the following counsel by certified mail, return receipt requested:

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The Honorable Robert L. Capers
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Dated: July 13, 2016

Jihoon Lee